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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,304	04/16/2001	Franz Josef Meyer-Almes	P66378US0	4840

136 7590 05/21/2003

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,304

Applicant(s)

MEYER-ALMES, FRANZ JOSEF

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: interview summary with Clontech and attached fax.

DETAILED ACTION

Amendment filed on 2-19-2003 is entered. Claims 12-26 are pending and examined on merits.

Priority

Acknowledgment is made of applicant's amendment to the specification, a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specification

The objection of the specification is withdrawn since applicant amended the specification.

Claim Rejections - 35 USC § 112

Rejection of claims under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps **is now applied to claims 12-22**. See MPEP § 2172.01. The omitted steps are: steps to accomplish the purpose stated in preamble of the claims. How is the chemosensitivity of cells is determined? Does the claims mean more apoptosis of cells is indicative of chemosensitive to the added substance? Less apoptosis means more sensitive? What is being measured to determine whether the cells are chemosensitive to a substance?

Rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** because applicant cancelled all of the claims and presented new claims without the specifically rejected limitations.

Rejection of claims under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had **possession** of the claimed invention is **now applied to the new claims 1-22-25**. The claims are still interpreted as drawn to a kit and a method of detecting apoptosis by measuring caspase activity by measuring fluorogenic or chromogenic change of **a genus of caspase substrate**.

Applicant argues that the Office has not the initial burden of providing support a rejection but this argument is not persuasive because instant specification does not describe any caspase other substrate than the ones used in the art but the claims are drawn to a genus of unpredictable or undiscovered substrates. Applicant does not argue that the inventor had possession the entire genus of caspase substrates.

Rejection of claims under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method using aminocoumarin-DEVD, does not reasonably provide enablement for any other fluorogenic or chromogenic substrate in the instant invention is now applied to the new claims 1-22, and 24-25.

Applicant argues that the instant specification meets the enablement requirement of the law and screening a protein for biological activity is routine, not undue experimentation. The argument is fully considered not found not persuasive because the rejection was not based on screening a protein for biological activity but based on the specification's teaching of only one art-available method, i.e, aminocouarin-DEVD based assay. However, the new claims 1-25 are broadly drawn to method using substrates the specification does not teach how to make and how to use.

The rejection under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for screening for possible new chemotherapy, does not reasonably provide enablement for any other purposes **is applied to the new claim 23**.

Applicant argues that the law does not require that the specification teach what is already known in the art and one skilled in the art knows what to do with the invention but these argument is not persuasive because the specification does not teach all the necessary methods to practice the full scope of the invention.

Claim Rejections - 35 USC § 102

Rejection of the claims under 35 U.S.C. 102(b) as being anticipated by either Benjamin et al (March 1998, Molecular Pharmacology 53, pages 446-450) or Martins et al (Dec. 1, 1997, Blood 90, pages 4285-4296) is now applied to the new claims 1-23.

Applicant argues that the instant invention is measuring accumulated caspase activity and the art of record does not measure accumulated activity. This argument has been fully considered not persuasive because Benjamin et al show method of measuring accumulated caspase activity more than 15 hours and Martins et al teach method of measuring accumulated caspase activity up to 48 hours (see the abstract).

The claims rejection under 35 U.S.C. 102(b) based upon a public use or sale of the invention is now applied to the new claims 24-26.

New claims 24-26 are still interpreted as drawn to kit for measuring caspase activity.

Applicant argues that catalog is printed in year 2000. The provided page printed in 2000 does not mean that the company began to sell the product in 2000. Interview with Ms. Huynh (from Clontech) conducted on 5-12-2003 provides that sale started in 1997. See the attached interview summary and the attached evidence.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

Claims 16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "characterized in..." but it is not clear what the means and bounds are for the limitation. What is being characterized in according to the recited claim?

Claim 16 recites the limitation "that pharmaceutically active substances" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recite "a solution of a reagent standardized for a total number of cells" but it is not clear what the metes and bound are?

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection. Applicant is requested to point out where in the specification as originally filed disclose applicant's invention is drawn to a kit comprising a solution of a reagent standardized for a total number of cells for measuring caspase activity.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu

May 19, 2003

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